

CLAIMS:

- 510 A1
1. A method of examining a biological sample for evidence of dysregulated cellular growth comprising comparing the status of 20P1F12/TMPRSS2 in the biological sample to the status of 20P1F12/TMPRSS2 in a corresponding normal sample, wherein alterations in the status of 20P1F12/TMPRSS2 in the biological sample are associated with dysregulated cellular growth.
2. The method according to claim 1, wherein the status of 20P1F12/TMPRSS2 in the biological sample is evaluated by examining levels of 20P1F12/TMPRSS2 mRNA expression or levels of 20P1F12/TMPRSS2 protein expression.
3. The method according to claim 1, wherein the status of 20P1F12/TMPRSS2 in the biological sample is evaluated by observing the presence or absence of a 20P1F12/TMPRSS2 immunoreactive complex.
4. The method according to claim 1, wherein the status of 20P1F12/TMPRSS2 in the biological sample is evaluated by a method selected from the group consisting of Southern analysis, northern analysis, polymerase chain reaction analysis and immunoassay.
5. The method according to claim 1, wherein the biological sample is selected from the group consisting of blood, serum, stool, urine, semen and biopsied tissue.
- 510 A2 25 16. The method according to claim 1, wherein the dysregulated cellular growth is indicative of a prostate cancer.
7. The method according to claim 1, wherein the dysregulated cellular growth is indicative of a colon cancer.
- 30 8. The method of claim 1, wherein the status of 20P1F12/TMPRSS2 in the biological sample is evaluated by an immunoassay which measures the concentration of a free 20P1F12/TMPRSS2 polypeptide, the concentration of 20P1F12/TMPRSS2 polypeptide complexed to a binding partner or the ratio comparing the concentration of

the free 20P1F12/TMPRSS2 polypeptide to the concentration of the 20P1F12/TMPRSS2 polypeptide complexed to a binding partner.

9. The method of claim 8, wherein the 20P1F12/TMPRSS2 evaluated in the biological sample is secreted from cells exhibiting dysregulated growth.

10. A method of identifying evidence of a neoplasm in a biological sample comprising:

(a) examining a level of 20P1F12/TMPRSS2 gene expression in a test biological sample; and

(b) comparing the level of 20P1F12/TMPRSS2 gene expression in the test biological sample to a level of 20P1F12/TMPRSS2 gene expression found in a comparable normal biological sample,

wherein differences in the level of 20P1F12/TMPRSS2 gene products in the test biological sample relative to the normal biological sample are associated with the neoplasm.

11. The method according to claim 10, wherein the neoplasm is a prostate cancer.

12. The method according to claim 10, wherein the neoplasm is a colon cancer.

13. The method according to claim 10, wherein the test biological sample is selected from the group consisting of blood, serum, stool, urine, semen and biopsied tissue.

14. The method according to claim 10, wherein the level of 20P1F12/TMPRSS2 gene expression in the test biological sample is evaluated by examining the level of 20P1F12/TMPRSS2 mRNA expression.

15. The method according to claim 10, wherein the level of 20P1F12/TMPRSS2 gene expression in the test biological sample is evaluated by examining the level of 20P1F12/TMPRSS2 protein expression.

16. The method according to claim 10, wherein the level of 20P1F12/TMPRSS2 gene expression in the test biological sample is evaluated by a method selected from the

group consisting of Southern analysis, northern analysis, polymerase chain reaction analysis and immunoassay.

5 17. The method of claim 10, wherein the level of 20P1F12/TMPRSS2 gene expression in a test biological sample is evaluated by an immunoassay which measures the concentration of free 20P1F12/TMPRSS2 polypeptide or the concentration of 20P1F12/TMPRSS2 polypeptide complexed to a binding partner.

10 18. The method of claim 17, wherein the 20P1F12/TMPRSS2 evaluated in the test biological sample is secreted from cells exhibiting dysregulated growth.

19. The method of claim 18, wherein the cells exhibiting dysregulated growth are prostate cancer cells.

15 20. A method of detecting a cancer in an individual comprising:
(a) examining 20P1F12/TMPRSS2 gene expression in a test biological sample obtained from the individual; and
(b) examining the individual for the presence of a factor associated with dysregulated cellular growth;
20 wherein a coincidence of 20P1F12/TMPRSS2 gene expression in the test biological sample obtained from the individual and the presence of the factor associated with dysregulated cellular growth is indicative of the cancer.

25 21. The method according to claim 20, wherein the cancer is a prostate cancer.

22. The method according to claim 20, wherein the cancer is a colon cancer.

30 23. The method according to claim 20, wherein the factor associated with dysregulated cellular growth is an increase in the level of prostate specific antigen expression.

24. The method according to claim 20, wherein the test biological sample is selected from the group consisting of blood, serum, stool, urine, semen and biopsied tissue.

25. The method according to claim 20, wherein the 20P1F12/TMPRSS2 gene expression in the test biological sample is evaluated by examining the level of 20P1F12/TMPRSS2 mRNA expression or the level of 20P1F12/TMPRSS2 polypeptide expression.

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26. The method according to claim 20, wherein the 20P1F12/TMPRSS2 gene expression in the test biological sample is evaluated by a method selected from the group consisting of Southern analysis, northern analysis, polymerase chain reaction analysis and immunoassay.

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27. The method of claim 20, wherein the 20P1F12/TMPRSS2 gene expression in a test biological sample is evaluated by an immunoassay which measures the concentration of free 20P1F12/TMPRSS2 polypeptide or the concentration of 20P1F12/TMPRSS2 polypeptide complexed to a binding partner.

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28. The method of claim 27, wherein the 20P1F12/TMPRSS2 evaluated in the test biological sample is secreted from cells exhibiting dysregulated growth.

29. A method of inhibiting the growth of a neoplastic cell that expresses 20P1F12/TMPRSS2 comprising contacting the 20P1F12/TMPRSS2 expressed by the neoplastic cell with an effective amount of an anti-20P1F12/TMPRSS2 antibody so that the growth of the neoplastic cell is inhibited.

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30. A method of inhibiting the progression of a neoplasm that expresses 20P1F12/TMPRSS2 comprising contacting the 20P1F12/TMPRSS2 expressed by the neoplasm with an effective amount of an anti-20P1F12/TMPRSS2 antibody so that the progression of a neoplasm is inhibited.

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31. The method of claim 30, wherein the antibody binds an epitope within a predominantly cell surface associated domain of 20P1F12/TMPRSS2.

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32. The method of claim 31, wherein the antibody is coupled to a cytotoxic agent.

